

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

ch

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/813,323	03/10/97	BALTIMORE	D 50659/JPW/JM

JOHN F WHITE
COOPER AND DUNHAM
1185 AVENUE OF THE AMERICAS
NEW YORK NY 10036

HM12/0523

EXAMINER

DAVIS, M

ART UNIT	PAPER NUMBER
----------	--------------

1642

24

DATE MAILED:

05/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.

08/813,323

Applicant(s)

Baltimore et al

Examiner

Minh-Tam Davis

Art Unit

1642



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 16, 2001
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3, 4, and 92 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3, 4, and 92 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other: _____

Art Unit: 1642

Effective February 7, 1998, the Group Art Unit location has been changed, and the examiner of the application has been changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Minh-Tam Davis, Group Art Unit 1642.

The request filed on 03/16/2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No: 08/813323 is acceptable and a CPA has been established. An action on the CPA follows.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Accordingly, claims 3, 4, 92 are being examined.

The following are the remaining rejections.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, NEW MATTER, NEW REJECTION

Claims 3, 4, 92 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 3, 4, 92 are drawn to a protein which comprises an amino acid sequence which a) is included in SEQ ID NO:1, b) has at its carboxy terminus a proline as shown at position number

Art Unit:

567 of SEQ ID NO:1, c) comprises continuous amino acids as shown in SEQ ID NO:1 between the proline at position number 567 and the serine at position number 385, and d) does not extend at its amino terminus beyond the serine shown in SEQ ID NO:1 at position number 324.

The specification discloses a protein comprising CRAF1 truncated by from about 323 to about 414 amino acid residues at the amino terminus (p.8, first paragraph).

Thus although the specification discloses truncation spanning from amino acid 323 to amino acid 414, the specification does not disclose nor contemplates truncation at the specific amino acid number 385.

**REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, ENABLEMENT, NEW
REJECTION**

Claims 3, 4, 92 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 3, 4, 92 are drawn to variants of a protein which comprises an amino acid sequence which a) is included in SEQ ID NO:1, b) has at its carboxy terminus a proline as shown at position number 567 of SEQ ID NO:1, c) comprises continuous amino acids as shown in SEQ ID NO:1 between the proline at position number 567 and the serine at position number 385, and d)

Art Unit:

does not extend at its amino terminus beyond the serine shown in SEQ ID NO:1 at position number 324. Said variants consist of substitutions wherein valine is substituted for glycine or vice versa.

The specification discloses that conservative substitutions include the substitution of one amino acid for another with similar characteristics, such as substitution of valine for glycine (p. 8, second paragraph). There is no disclosure whether there is retention of the activity of the claimed variant proteins. Although conservative substitutions increase the chance of having less effect on the activity of the protein, it is unpredictable which amino acid at a certain position could be substituted even by conservative substitution. For example, Straub P et al, 1993, J Biol Chem 268(29): 21997-20003, teach that conservative substitutions of valine for glycine at positions 111 and 117 of cytochrome P450 2C2 result in about 50- and 7-fold reduction of activity, respectively. Kouklis PD et al, 1993, J Cell Science, 106(pt 3): 919-28, teach that a single exchange of glycine 450 of the intermediate filament protein vimentin with valine strongly interferes with the normal assembly of the intermediate filaments.

In view of the above, it would be undue experimentation for one of skill in the art to practice the claimed invention.

REJECTION UNDER 35 USC 102

Rejection under 35 USC 102(b) of claims 3, 4, and 92, pertaining to anticipation by Sato et al remains for reasons already of record in paper No.21.

Art Unit:

Applicant amends claim 92 to recite a protein which comprises an amino acid sequence which a) is included in SEQ ID NO:1, b) has at its carboxy terminus a proline as shown at position number 567 of SEQ ID NO:1, c) comprises continuous amino acids as shown in SEQ ID NO:1 between the proline at position number 567 and the serine at position number 385, and d) does not extend at its amino terminus beyond the serine shown in SEQ ID NO:1 at position number 324.

Applicant argues that the TRAF domain of amino acids 384-540 taught Sato et al is not the same as the claimed protein, because the amino acid 384 of the sequence taught by Sato et al is the same as amino acid 386 of SEQ ID NO:1.

Applicant's arguments set forth in paper No.23 have been considered but are not deemed to be persuasive for the following reasons:

The protein comprising residues 363-543 taught by Sato et al meets all the limitation of the claims. Said protein comprises an amino acid sequence which a) is included in SEQ ID NO:1, b) has at its carboxy terminus a proline as shown at position number 567 of SEQ ID NO:1, c) comprises continuous amino acids as shown in SEQ ID NO:1 between the proline at position number 567 and the serine at position number 385, and d) does not extend at its amino terminus beyond the serine shown in SEQ ID NO:1 at position number 324.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Minh-Tam B. Davis whose telephone number is (703) 305-2008. The

Art Unit:

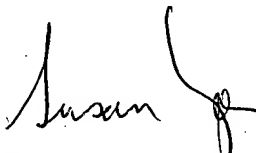
examiner can normally be reached on Monday-Friday from 9:30am to 3:30pm, except on Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tony Caputa, can be reached on (703) 308-3995. The fax phone number for this Group is (703) 308-4227.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0916.

Minh-Tam B. Davis

May 15, 2001



SUSAN UNGAR, PH.D
PRIMARY EXAMINER